

From: Hooban, Christopher
Sent: Tuesday, April 28, 2015 8:30 AM
To: 'Stanley.ammons@octapharma.com'
Cc: Cagungun, Nannette
Subject: Request for Information - SDTM: BL 125077/332; Original BLA; Octapharma;
ADD 14-APR-2016

Our Reference: BL 125077/332
Product: Immune Globulin Intravenous (Human) 10%, Panzyga
Indications: 1) Primary humoral immunodeficiency and 2) Chronic immune thrombocytopenic purpura

Dear Mr. Ammons:

Good morning. This email is in reference to your original BLA submitted on April 15, 2015 for Immune Globulin Intravenous (Human) 10%. The FDA would like to request information on the study data tabulation model (SDTM) used within the submission, specifically which version of SDTM was used to create the SDTM datasets. If you have any questions please contact me at (240)402-8376 or at christopher.hooban@fda.hhs.gov. Thanks for your time.

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